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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,247	07/28/2006	Yoshihisa Amano	DK-US055218	8897
22919 7590 01/25/2008 GLOBAL IP COUNSELORS, LLP 1233 20TH STREET, NW, SUITE 700 WASHINGTON, DC 20036-2680			EXAMINER DIRAMIO, JACQUELINE A	
			ART UNIT 1641	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/552,247	Applicant(s) AMANO ET AL.	
	Examiner Jacqueline DiRamio	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 5-10, 13, 14 and 19-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 11, 12 and 15-18 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____  |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :10/6/05; 8/7/06; 11/14/06; 11/1/07 .

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I, including Species A(i) and B(ii), which includes claims 1 – 4, 11, 12 and 15 – 18, in the reply filed on October 31, 2007 is acknowledged.

Claims 5 – 10, 13, 14, and 19 – 26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions.

### ***Claim Objections***

Claim 4 is objected to because of the following informalities:

Claim 4 recites the term "ncludes," which appears to be an incorrect spelling of "includes."

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the phrase "a receptor molecule specifically binding with the particular material in the air," which is vague and indefinite because it appears the

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"receptor molecule" is actually "capable" of "specifically binding" with the "particular material," given the fact that this claim is a recitation of a sensor and not a method step.

Claim 1 further recites the phrase "a polymer molecule having an altered light absorbency due to the binding of the particular material and the receptor material," which is vague and indefinite because the "polymer molecule" should have the altered light absorbency after the binding of the particular material, which occurs during the use of the sensor. Therefore, perhaps the claim should recite "a polymer molecule that undergoes an altered light absorbency upon the binding of the particular material to the receptor material."

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 – 4, 11, 12, 15, 16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Charych et al. (US 2001/0026915).

Charych et al. teach a colorimetric sensor for detecting a particular analyte (material) in the air, comprising:

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a receptor molecule capable of specifically binding with the particular analyte in the air; and

a polymer molecule that undergoes an altered light absorbency due to the binding of the particular analyte and the receptor molecule (see paragraphs [0008]-[0013], [0018], [0022]-[0024], [0135]-[0137], and [0140]).

With respect to Applicant's claim 2, the receptor molecule is linked to the polymer molecule at a portion of the receptor molecule not participating in binding with the particular analyte (see Figures 1 and 2; and paragraphs [0011] and [0184]).

With respect to Applicant's claim 3, the altered light absorbency of the polymer molecule is caused by a molecular structural alteration in the polymer molecule (see paragraphs [0022] and [0052]).

With respect to Applicant's claim 4, the polymer molecule can include polydiacetylene (see paragraphs [0133] and [0176]).

With respect to Applications claim 11, the receptor molecule can comprise sialic acid, ganglioside, antibodies, and antibody fragments (see paragraphs [0009] and [0013]).

With respect to Applicant's claims 12, 15 and 16, the sensor can include a water-retaining means in the form of an absorbent polymer that can comprise a cellulose derivative, i.e. nitrocellulose (see paragraphs [0137], [0209] and [0211]).

With respect to Applicant's claim 18, the polymer molecule can be modified in many ways, including creating a water-soluble polymeric molecule or one with

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increased hydrophilicity (see paragraphs [0010], [0018], [0041], [0091], [0093], and [0140]).

Claims 1 – 4 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Charych et al. (US 6,001,556).

Charych et al. teach a colorimetric sensor for detecting a particular analyte (material), comprising:

a receptor molecule capable of specifically binding with the particular analyte; and

a polymer molecule that undergoes an altered light absorbency due to the binding of the particular analyte and the receptor molecule (see Figure 1; and column 4, lines 19-67; column 5, lines 1-14; column 13, lines 59-61; and column 14, lines 1-39).

With respect to Applicant's claim 2, the receptor molecule is linked to the polymer molecule at a portion of the receptor molecule not participating in binding with the particular analyte (see Figure 1; and column 14, lines 1-19).

With respect to Applicant's claim 3, the altered light absorbency of the polymer molecule is caused by a molecular structural alteration in the polymer molecule (see column 14, lines 33-39).

With respect to Applicant's claim 4, the polymer molecule includes polydiacetylene (see column 15, lines 60-67; and column 16, lines 1-2).

With respect to Applications claim 11, the receptor molecule can comprise sialic acid and various peptides (see column 8, line 67; column 9, lines 1-6; and column 15, lines 2-33).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Charych et al. (US 2001/0026915) in view of R. Freake et al. (US 3,843,452).

The Charych et al. reference, which was discussed in the first 102(b) rejection above, fails to teach that the cellulose derivative comprises one of those listed in Applicant's claim 17.

R. Freake et al. teach a microbiological test article comprising a laminated structure, wherein the laminated structure comprises an absorbent web and a



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microporous membrane. A test material, such as a chemical or biochemical reagent, can be effectively incorporated on or in the membrane or web, wherein a microbiologically inert colloidal material can be included with the reagents to facilitate the rehydration of the reagent after contact with a fluid being tested. Preferred colloidal materials include cellulose gums, such as methylcellulose (see Figures; column 2, lines 25-35; column 4, lines 42-75; and column 5, lines 1-26).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Charych et al. the use of methylcellulose as a cellulose derivative for the absorbent material as taught by R. Freake et al. because R. Freake et al. teach that cellulose gums, such as methylcellulose, can be effectively used to incorporate various biochemical reagents into a laminated test article comprising an absorbent web and microporous membrane in order to facilitate the rehydration of the reagent after contact of the test article with a fluid being tested.

### ***Conclusion***

No claims are allowed.

The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure:


Reppy et al. (US 6,984,528); and

Jo et al. (US 6,277,652).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Jackie DiRamio  
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